

**DECLARATION Under 37 CFR § 1.132**

Docket No. MCA 633

Applicant: Anthony DiLeo
Serial No: 10/784,330
Filed: February 23, 2004
For: Fluid Dispensing Apparatus Having Means For Measuring Fluid Volume
Continuously
Examiner: Joseph A. Kaufman
Art Unit: 3754

The undersigned hereby declare and state:

1. I am the named inventor in the above-identified United States patent application.
2. I am a Development Engineer and Principal Consultant for Millipore Corporation. I have 20 plus years experience engineering and designing materials and equipment for the biopharmaceutical and bioprocessing industries and am a named inventor on more than 16 issued U.S. patents.
3. I understand that the Examiner in this case has rejected claims 1, 2, 4-6 and 11-15 under 35 U.S.C. § 103 in view of U.S. Patent Nos. 5,680, 960 (hereinafter "Keyes"); 5,135,485 (hereinafter "Cohen"); and 6,299,020 (hereinafter, "Sudolcan").
4. The Examiner in this case alleges Keyes discloses all of the structure of claims 1, 2, 4, and 6, but admits that Keyes fails to disclose a pair of copper electroconductive terminals proximate the fill tube and control means responsive to the capacitance of the conductors for controlling the filling or release of fluid from the reservoir. The Examiner believes that Keyes does disclose a pair of optical terminals and a control means responsive to the optical terminals for controlling the filling or release of fluid from the reservoir. The Examiner alleges that Cohen teaches a fluid sensing system having a pair of electroconductive terminals placed directly on the container. The Examiner believes that it would

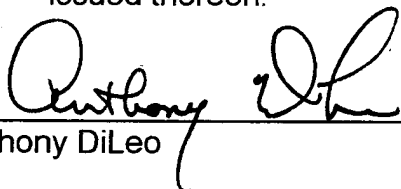
have been obvious for a skilled artisan at the time the invention was made to replace the optical sensors of Keyes with the electroconductive terminals taught by Cohen because Sudolcan recognizes that optical sensors can have deficiencies when the material to be dispensed is less opaque and that electroconductive terminals are more reliable for these types of materials..

5. I am familiar with the Volumetric Fluid Dispensing Apparatus described in Keyes and am particularly familiar with the optical sensors described in Keyes as well as the sensing mechanisms described in both the Sudolcan and Cohen patents. I have conducted experiments using the apparatus described in the Keyes patent and have built a working model of the apparatus described in the instant application and conducted experiments with it as well.
6. The instant invention provides a fluid dispensing apparatus for dispensing a predetermined volume of fluid comprising in part a pair of electroconductive terminals proximate either the fill tube assembly or the fluid reservoir and means for connecting the terminals to an energy source so that a current can be passed from one terminal to the other terminal; and control means responsive to the capacitance of the current for selectively controlling the dispensing of fluid from the tube assembly, or the introduction of fluid from the reservoir, or the release of fluid from the reservoir.
7. Providing control means responsive to the capacitance of the current provides surprising and unexpected benefits compared to the device described in Keyes. Based on the experiments I have conducted I have concluded that the Keyes device has several shortcomings regarding the accuracy of the volume it dispenses. Keyes depends on optically monitoring the fluid level in the fill tube to control the volume of the dispensed aliquot. The optical system provided in Keyes does not provide real time monitoring of fluid levels. In practice this means that there will be a delay between the time the optical sensors sense the

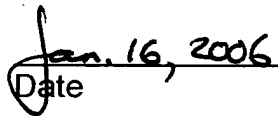
desired volume is present in the fill tube and the time the valve controlling flow to the fill tube is shut off. The result is that the fill tube volume in the Keyes system will overshoot the sensor location resulting in an inaccurately dispensed volume. To overcome this deficiency it is necessary to precalibrate the Keyes system such that the overshoot in the fill tube is compensated for. This recalibration step will be required for each new fluid because viscosity differences will result in different fluid velocities and therefore different degrees of overshooting the desired mark (i.e. dispensed volume). Additionally, flow rate from the reservoir to the fill tube is governed by the head height of the fluid in the reservoir. But the precalibration for a batch run necessarily assumes a constant head height. Thus, additional inaccuracies in dispensed volume occur as the head height in the fluid reservoir decreases as the system operates over the course of a batch run. The result is that the Keyes system provides for fluid aliquots which will be dispensed over a range of volumes over a single batch run, instead of providing for a precise dispensed volume in each sample of a batch run.

8. Surprisingly, the use of capacitance to measure fluid volume in the fill tube overcomes the shortcomings associated with the Keyes device. It provides for the real time continuous monitoring of fluid levels which may be dispensed from the fill tube assembly and thus provides for the calculation of fluid velocity entering the fill tube. Once calculated the fluid velocity can be used to determine volume in the fill tube. Thus the fill tube may be filled independently of the head height in the fluid reservoir and independent of the viscosity of the dispensed fluid. Overshoot in fill tube volume may be compensated for through feedback control, and does not depend on a preset calibration. The result is an accurate calculation of dispensed fluid volume is obtained without the need for precalibration or the consequence of inaccuracies from sample to sample within a batch run due to reliance on a preset calibration. Moreover, there is no need for recalibration from fluid to fluid to account for different viscosities.

9. Using capacitance to measure the real time fluid level in the fill tube would allow for a system that provides for fill rates to be maintained over the course of a batch run. Because fluid velocity is used to determine the fluid volume, the fluid reservoir height could be made adjustable such that the fill rate over time (i.e., as the head height in the reservoir decreases) could be maintained in instances where the run-time for a batch is critical.
10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Anthony DiLeo



Date